K121100

BIOMÉRIEUX

## 510(k) SUMMARY

## VITEK® 2 AST *Streptococcus* Vancomycin

NOV 19 2012

**510(k) Submission Information:**

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|---|---|
| Submitter's Name: | bioMérieux, Inc. |
| Address: | 595 Anglum Road<br>Hazelwood, MO 63042 |
| Contact Person: | Jocelyn Jennings<br>Senior Manager, Regulatory Affairs |
| Phone Number: | 919-620-2894 |
| Fax Number: | 919-620-2548 |
| Date of Preparation: | April 5, 2012 |

**B. Device Name:**

| | |
|---|---|
| Formal/Trade Name: | VITEK® 2 AST *Streptococcus* Vancomycin<br>(≤ 0.125 – 8 µg/ml) |
| Classification Name: | Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645 |
| Common Name: | VITEK 2 AST-ST Vancomycin |

**C. Predicate Device:** VITEK 2 AST-GP Amoxicillin K063597

**D. 510(k) Summary:**

VITEK® 2 AST *Streptococcus* Vancomycin is designed for antimicrobial susceptibility testing of Streptococcus species. VITEK® 2 AST *Streptococcus* Vancomycin is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Vancomycin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active *in vitro* and in clinical infections
Viridans group streptococci

*In vitro* data are available, but their clinical significance is unknown
*Streptococcus agalactiae*
*Streptococcus pyogenes*

The antimicrobial presented in VITEK 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The bacterial isolate to be tested is diluted to a standardized concentration in 0.45 - 0 .50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System automatically fills, seals and places the card into the incubator/reader. The VITEK 2 Compact has a manual filling and sealing operation. The VITEK 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antibiotic contained on the card.

VITEK 2 AST *Streptococcus* Vancomycin demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA, Issued August 28, 2009.

The Premarket Notification [510(k)] presents data in support of VITEK 2 AST *Streptococcus* Vancomycin. An external evaluation was conducted with fresh clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK 2 AST *Streptococcus* Vancomycin by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK 2 and VITEK 2 Compact instrument platforms. VITEK 2 AST *Streptococcus* Vancomycin demonstrated acceptable performance of 100% overall Category Agreement. Reproducibility and Quality Control demonstrated acceptable results using both the VITEK 2 and VITEK 2 Compact instrument systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

bioMerieux, Inc.
C/O Jocelyn Jennings, Senior Manager, Regulatory Affairs
595 Anglum Road
Hazelwood MO 63042

NOV 19 2012

Re: K121100
VITEK®2 AST Streptococcus Vancomycin
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: Class II
Product Code: LON
Dated: November 8, 2012
Received: November 9, 2012

Dear Ms. Jennings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): k121100

Device Name: VITEK® 2 AST *Streptococcus* Vancomycin
(≤ 0.125 – 8 µg/mL)

Indications For Use:

VITEK® 2 AST *Streptococcus* Vancomycin is designed for antimicrobial susceptibility testing of Streptococcus species. VITEK® 2 AST *Streptococcus* Vancomycin is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Vancomycin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active *in vitro* and in clinical infections
Viridans group streptococci

*In vitro* data are available, but their clinical significance is unknown
*Streptococcus agalactiae*
*Streptococcus pyogenes*

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 System for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus spp.* and clinically significant yeast.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k121100